

#### **REMARKS**

In accordance with the above amendments, claims 34, 36, 43, 46, 49 and 50 have been amended and claims 35, 40-41 have been canceled. Thus, claims 19-23, 34, 36-39 and 42-51 remain under consideration in this application. No claim has yet been allowed.

#### **Claim Rejections - 35 USC § 112**

Rejections under 35 USC § 112 involved the use of the term "a major fraction" in claim 36 and the term "a lightly adhering" in claim 49 which, in the Examiner's view, rendered these claims indefinite.

While applicants do not agree, these terms have been deleted from the claims and, therefore, this rejection is believed to have been rendered moot.

#### **Claim Rejections - 35 USC § 103**

It is noted that all of the claims stand rejected under 35 USC § 103(a) as being unpatentable over Marcenyac et al (U.S. Patent Publication No. 2004/0146547 A1) and Granger et al (USPN 5,149,538) in view of Church (USPN 6,660,901). This rejection is respectfully traversed.

As has previously been explained, the present invention as claimed as fundamentally different from Marcenyac et al because of the fundamental difference in the active agent in the anti-abuse composition and other considerations previously enumerated. Furthermore, applicants cannot agree with the Examiner's position

that unless the reference teaches the exclusion of a suitable specific anti-abuse substance, it is clearly contemplated by the reference. Clearly, MPEP § 2112.01 does not apply to the present facts inasmuch as the claimed composition is not identical or substantially identical to that disclosed in the reference. The preferred and claimed anti-abuse composition requires activated carbon and, as previously explained, this well may not be compatible with dyes and other ingredients touted and preferred by Marcenyac et al. Such materials cannot be used with the anti-abuse substance of the present invention.

Granger is seen to disclose a transdermal adhesive patch which includes an opioid and an anti-abuse substance to attenuate the euphorogenic effect of the opioid. These materials are separated by a permanent impermeable barrier means in his device which the Examiner has equated to applicants' impermeable separator membrane which is connected to an element that causes its removal when the patch is removed. This embodiment is found in independent claim 49, and in claims 19-23 and 50-51 which depend in some way from claim 49. Descriptive material is cited at column 3, lines 25-40, of Granger and the barrier means of Granger is seen to read on the impermeable separator membrane of the present claims. Applicants believe that this position clearly represents an inaccurate reading of the disclosure of Granger et al and ignores specific language describing the

separator membrane and attached extension device of applicants' claims.

The separator membrane in Granger is a permanent part of the structure in that device. It is not designed to be removed in any case. The antagonist substance in Granger et al must diffuse through the top barrier 1 and is clearly designed not to be released unless the dosage form is ingested or immersed in a solvent. The barrier means 2 is never removed from between the antagonist layer and the opioid layer. There is no extension device provided for such removal as is required in the present claims. In fact, the barrier layer 2 in Granger et al cannot be removed without destroying their device. Thus, Granger et al clearly neither teach nor suggest the use of a removable barrier, let alone, a removable barrier that is automatically removed upon removal of the patch from the skin of a user.

Church (USPN 6,660,901 B2) discloses a patch for topical application to the skin which contains an activated charcoal composition to absorb toxins, bacteria, fungus, carcinogens and other harmful pathogens in the treatment of bites, stings, injuries, disease and other disorders. That application has nothing to do with utilizing activated carbon as an anti-abuse substance for treating residual opioid substances, or the like. In that reference, the activated charcoal is the active ingredient itself and there is no abusable substance involved. There is no teaching or suggestion that it would be useful in the

manner and in the particular application of the present invention. In particular, the Church reference does not imply, teach or suggest that activated carbon could bind a substance such as an absorbable substance in a sufficiently tenacious manner to preclude attempted recovery of that absorbable substance by a later extraction process as the present applicants have discovered.

Contrary to the Examiner's view, applicants believe that the combination of Marcenyac et al and Granger et al clearly do not meet the claim limitations of the present invention except for the use of activated carbon and Church fails to address the deficiencies of those two references. Thus, applicants believe that the present claims are, in fact, clearly patentably distinct from this combination and could not have been conceived without a clear inventive step over such combination.

In view of the above amendments, taken together with the remarks herein, the Examiner is respectfully requested to reconsider his position, withdraw the rejections and allow all of the claims.

Should issues remain which, in the opinion of the Examiner, could be addressed by telephone interview, he is invited to

contact the undersigned attorney at his convenience to discuss same in an effort to resolve them and expedite prosecution of this application.

Respectfully submitted,  
NIKOLAI & MERSEREAU, P.A.



C. G. Mersereau  
Registration No. 26,205  
900 Second Avenue South  
Suite 820  
Minneapolis, MN 55402  
Telephone: (612) 339-7461